SENATE BILL NO. 137

INTRODUCED BY S. FITZPATRICK

A BILL FOR AN ACT ENTITLED: “AN ACT ESTABLISHING THE PRESCRIPTION DRUG COST TRANSPARENCY ACT; ESTABLISHING REPORTING REQUIREMENTS FOR PRESCRIPTION DRUG MANUFACTURERS, PHARMACY BENEFIT MANAGERS, AND HEALTH INSURANCE ISSUERS; REQUIRING ESTABLISHMENT OF A WEBSITE FOR PRESCRIPTION DRUG COST INFORMATION; PROVIDING PENALTIES; PROVIDING RULEMAKING AUTHORITY; AND PROVIDING A DELAYED EFFECTIVE DATE.”

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MONTANA:

NEW SECTION. **Section 1. Short title.** [Sections 1 through 7] may be cited as the "Montana Prescription Drug Cost Transparency Act".

NEW SECTION. **Section 2. Definitions.** As used in [sections 1 through 7], the following definitions apply:

(1) "Animal health product" means a medical product approved and licensed for use in animal or veterinary medicine, including a pharmaceutical, a biologic, an insecticide, and a parasiticide.

(2) "Brand name" has the meaning provided in 37-7-502.

(3) "Generic name" has the meaning provided in 37-7-502.

(4) "Health benefit plan" means an individual, blanket, or group plan, policy, contract, certificate, or agreement entered into, offered, or issued by a health insurance issuer to provide, deliver, arrange for, pay for, or reimburse any of the costs of health care services.

(5) "Health insurance issuer" has the meaning provided in 33-22-140.

(6) (a) "Pharmaceutical drug manufacturer" means an entity engaged in the business of producing, preparing, propagating, compounding, converting, processing, packaging, labeling, or distributing a prescription drug.

(b) The term does not include:

(i) a wholesale distributor as defined in 37-7-602;

(ii) a retailer of prescription drugs; or

(iii) a pharmacist as defined in 37-7-101.

(7) "Pharmacy benefit manager" has the meaning provided in 33-22-170.

(8) (a) "Prescription drug" has the meaning provided in 37-7-101.

(b) The term does not include a device or an animal health product.

(9) "Rebate" means any formulary discount or concession attributable to the utilization of prescription drugs in the state of Montana that is paid by a pharmaceutical drug manufacturer to a pharmacy benefit manager after the pharmacy benefit manager processes a claim from a pharmacy.

(10) "Wholesale acquisition cost" has the meaning provided in 42 U.S.C. 1395w-3a.

NEW SECTION. **Section 3. Disclosure of prescription drug pricing information.** (1) No later than ~~January 15~~ JULY 1 each year, a pharmaceutical drug manufacturer shall submit a report to the commissioner stating the current wholesale acquisition cost information for the United States food and drug administration-approved prescription drugs sold in or into this state by the manufacturer.

(2) The commissioner shall develop a website to provide the public with the wholesale acquisition cost information submitted under subsection (1). The website must be made available on the department's website with a dedicated link that is prominently displayed on the home page or by a separate, easily identifiable internet address.

(3) (a) A pharmaceutical drug manufacturer shall submit a report providing the information required in subsection (3)(b) for each prescription drug for which the wholesale acquisition cost has increased by:

(i) 30% or more over the average wholesale acquisition cost for the preceding 3 years; or

(ii) 10% or more over the wholesale acquisition cost in the preceding calendar year.

(b) The report required under this subsection (3) must include the following information:

(i) the name of the prescription drug;

(ii) whether the drug is a brand-name drug or generic-name drug;

(iii) the effective date of the change in the wholesale acquisition cost;

(iv) aggregate, company-level research and development costs for the most recent year for which final audit data is available;

(v) the name of each of the pharmaceutical drug manufacturer's prescription drugs approved by the United States food and drug administration in the previous 3 calendar years;

(vi) the name of each of the pharmaceutical drug manufacturer's prescription drugs that lost patent exclusivity in the United States in the previous 3 calendar years; and

(vii) ~~all factors that caused the increase in the wholesale acquisition cost, the percentage of the total increase in the cost that is attributable to each factor, and an explanation of the role of each factorin contributing to the increase in the wholesale acquisition cost~~ A STATEMENT REGARDING THE FACTOR OR FACTORS THAT CAUSED THE INCREASE IN THE WHOLESALE ACQUISITION COST AND AN EXPLANATION OF THE ROLE OF EACH FACTOR'S IMPACT ON THE COST.

(c) A report required under this subsection (3) must be submitted to the commissioner within 30 days of the effective date of the increase in the wholesale acquisition cost.

(4) The quality and types of information and data that a pharmaceutical drug manufacturer submits to the commissioner under subsection (3) must be consistent with the quality and types of information and data that the manufacturer includes in the manufacturer's annual consolidated report on securities and exchange commission form 10-K or any other public disclosure.

(5) The commissioner shall publish the report on the website provided for in subsection (2). Publication must occur within 60 days of the commissioner's receipt of the report.

NEW SECTION. **Section 4. Pharmacy benefit manager information.** (1) No later than ~~June 1~~ JULY 1 each year, each pharmacy benefit manager doing business in this state shall file a report with the health insurance issuer with which the pharmacy benefit manager has a contract. The report must state for the immediately preceding calendar year the following information attributable to patient utilization of prescription drugs covered by health benefit plans in Montana:

(a) the aggregated dollar amount of rebates collected from pharmaceutical drug manufacturers; and

(b) the aggregated dollar amount of rebates collected from pharmaceutical drug manufacturers that were:

(i) passed on to health insurance issuers or to insureds at the point of sale of a prescription drug; and

(ii) retained by the pharmacy benefit manager.

(2) A report submitted by a pharmacy benefit manager may not disclose the identity of a specific health benefit plan or enrollee, the price charged for a specific prescription drug or class of prescription drugs, or the amount of any rebate provided for a specific prescription drug or class of prescription drugs.

(3) Pharmacy benefit manager reporting information obtained by the commissioner under [sections 1 through 7] through any means is a trade secret and may not be:

(a) disclosed pursuant to any public records requests, including those made pursuant to Title 2, chapter 6; or

(b) shared through interagency transfer.

NEW SECTION. **Section 5. Health insurance issuer information.** No later than ~~June 15~~ JULY 1 each year, a health insurance issuer shall report the following information to the commissioner for the prescription drugs reimbursed by the issuer in the previous calendar year:

(1) the 25 most frequently prescribed drugs under both the health benefit plan's medical benefit plans and pharmacy benefit plans;

(2) the 25 drugs that caused the greatest increase in total plan spending over the prior calendar year for both the health benefit plan's medical benefit plans and pharmacy benefit plans; and

(3) the impact of the cost of prescription drugs on each premium dollar, under both the health benefit plan's medical benefit and the pharmacy benefit plans.

NEW SECTION. **Section 6. Rulemaking authority.** The commissioner may adopt rules necessary to implement the provisions of [sections 1 through 7].

NEW SECTION. **Section 7. Penalties.** (1) A pharmaceutical drug manufacturer may be subject to the penalties provided for in 33-1-317 for:

(a) failing to timely submit reports or notices;

(b) failing to provide information required under [sections 1 through 7];

(c) failing to respond in a timely manner to a written request by the commissioner for additional information under [sections 1 through 7]; or

(d) knowingly providing inaccurate or incomplete information under [sections 1 through 7].

(2) (a) The commissioner shall collect the penalties provided for in this section. Penalties are due and payable 10 days after they are assessed.

(b) Money from the penalties must be used to offset the costs of administering [sections 1 through 7]. Excess money from the penalties must be deposited in the general fund.

(3) The commissioner may remit or mitigate a penalty upon terms and conditions the commissioner considers proper and consistent with the public health and safety.

NEW SECTION. **Section 8. Codification instruction.** [Sections 1 through 7] are intended to be codified as an integral part of Title 33, chapter 22, and the provisions of Title 33, chapter 22, apply to [sections 1 through 7].

NEW SECTION. **Section 9. Effective date.** [This act] is effective January 1, 2022.

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